

### **REMARKS**

Claims 1-9, 11-17 and 22-26 are pending in the present application. Claim 26 is withdrawn from consideration. Claims 1-6, 8, 9, 11-17 and 22-25 stand rejected. By this response, claims 1, 7, 22 and 23 are amended.

With respect to claim amendments, Applicants have not dedicated to the public or abandoned any unclaimed subject matter and have not acquiesced to any rejections or objections by the Patent Office. Applicants expressly reserve the right to pursue prosecution on any presently excluded subject matter in one or more future continuation and/or divisional application(s).

Reconsideration is respectfully requested in light of the above amendments and the following remarks. For the Examiner's convenience, Applicants' remarks are presented in the same order in which they were raised in the Office Action.

#### **Claims Amendments**

Claim 1 is amended to specify that the microneedle structure is formed of a second layer of photoresist material. Support for claim 1, as amended, is found at 16, lines 15-30 and Figures 3A-3E of the specification.

Claim 7 is amended to correspond to the limitations of amended claim 1, from which it depends. Claim 7 had been judged by the Examiner to include allowable subject matter.

Claims 22 and 23 are amended to specify hardening of moldable materials by soft lithography. Support for the amendments are found at pages 8-9 (and throughout) of the Specification and the originally filed claims.

No new matter is added. Entry of the amendments is respectfully requested.

#### **Claim Rejections – 35 USC § 103**

(i) Claims 1-3, 5, 8, 9, 11-13 and 15-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (see Figs. 6-8 and paragraphs 0144-0149; also see paragraph 0158).

Applicants note that Park *et al.* has a filing date of December 14, 2001 which is several months later than the March 14, 2001 filing date of the parent application 09/ 808,534 (now

issued as US Pat. No. 6,663,820), of which the present application is a divisional and the present application is entitled to the priority date of its parent.

Applicants further submit that Park is a non-provisional of provisional patent application No. 60/255,063 filed Dec. 14, 2000. However, the provisional application does not include disclosure corresponding to paragraphs [0147]-[0149] and [0158] and figure 8. Therefore, these sections of Park are not available as "prior" art available for the basis of rejection of the claims in the present application.

Applicants have amended claim 1 to specify a "method for fabricating microneedles, said method comprising: (a) providing a substrate material; (b) coating said substrate material with a first layer of a photoresist material; (c) *coating said first layer of photoresist material with a second layer of photoresist material; (d) patterning said second layer of photoresist material photoresist material with a plurality of microstructures by use of a photolithography procedure;* and (e) separating said patterned first and second layer of photoresist material from said substrate material, thereby *creating a microneedle structure comprised of patterned photoresist material containing said plurality of microstructures.*" (emphasis added).

Applicants submit that Park does not teach or suggest "creating a microneedle structure comprised of patterned photoresist material containing said plurality of microstructures," as specified in amended claim 1.

Park, at paragraphs 0144-0149, and Figures 6-8, discloses forming a plurality of photoresist microstructures onto a silicon wafer substrate. The Examiner agrees that Park does not teach separation of the photoresist layer from the silicon substrate. Even if "separation" per se was an obvious modification, Applicants submit that separation would result only in each individual microstructure being removed from the substrate (*see* Figs 6d, 7, 8b) as each microstructure is a free-standing structure on the substrate. Park does not disclose how to generate "a patterned photoresist material containing said plurality of microstructures," as specified in amended claim 1.

To clarify the invention of claim 1, Applicants have amended the claim to specify that a first layer of photoresist material is then covered with a second layer of photoresist material and microneedle structures are created on the second layer. When the photoresist material (both layers) is separated from the substrate a patterned photoresist material with the first layer as base and the photolithographically-generated microstructures on the second layer, together form "a

patterned photoresist material containing said plurality of microstructures," as specified in amended claim 1. (Specification, page 16, Figure 3). Park does not teach or suggest use of a second layer of photoresist material. Park does not teach or suggest creating a "a patterned photoresist material containing said plurality of microstructures," and thus there would be no teaching or suggestion or motivation to modify Park by introducing a second layer of photoresist material.

Since Park does not teach or suggest each and every limitation of claim 1, as amended, and since the differences are not obvious modifications of Park, Applicants submit that a *prima facie* case for obviousness has not been met and respectfully request withdrawal of this ground for rejection of claim 1, and claims that depend therefrom.

Regarding the grounds for rejection of independent claims 9 and 11, Applicants respectfully traverse. The Examiner admits that Park does not disclose "allowing such moldable material to harden using a soft lithography technique." Applicants note that Park discloses the formation of a polydimethylsiloxane (PDMS) mold based on the photoresist structures on the substrate and the formation of polymeric structure (polylactide) by "drying and melting under vacuuming." (See Park, paragraphs 0144, 0146, Figs. 6, 7).

The Specification, (paragraph bridging pages 8-9), defined the term "soft lithography: as used in this invention as:

The present invention not only uses photolithography for patterning certain structures, but also uses "soft lithography" for creating structures in three dimensions using molds made of a polymer material or similar non-metallic material. The soft lithography is a methodology in which all members involved share a common feature in that they use a patterned elastomer as the mask, stamp, or mold. (*citation omitted*) This elastomeric stamp or mold transfers its pattern to the "moldable material" which can comprise flexible organic molecules or other materials, rather than rigid inorganic materials now commonly used in the fabrication of microelectronic systems. In the present invention, such soft lithography processes are utilized in almost every methodology for creating an array of microneedles.

Park does not teach or suggest the use of "soft lithography" that are compatible with "all members involved shar[ing] a common feature in that they use a patterned elastomer as the mask, stamp, or mold, " a moldable material comprising flexible organic molecules.

Since Park does not teach or suggest each and every limitation of claims 9 and 11, as amended, and since the differences are not obvious modifications of Park, Applicants submit that a *prima facie* case for obviousness has not been met and respectfully request withdrawal of this ground for rejection of claims 9 and 11, and claims that depend therefrom.

(ii) Claims 6 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of Smith (see 49 and 50 in Fig. 3).

The Examiner cites Smith for disclosing the generation of break-away microneedles by etching a portion of microneedles.

As discussed above, Park does disclose each and every limitation of claim 1, as amended. Neither does Smith. Claim 6 depends from claim 1.

Regarding claim 22, Park does not teach or suggest hardening of the moldable materials by soft lithography as specified in amended claim 22. Neither does Smith.

Therefore, Applicants respectfully request withdrawal of this ground for rejection.

(iii) Claims 4, 14 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of Prausnitz et al -211 (see passage bridging columns 21 and 22; see col. 8, lines 45+ and col. 16, lines 46-49).

The Examiner cites Prausnitz for disclosing the use of a sacrificial layer.

As discussed above, Park does disclose each and every limitation of claim 1, as amended. Neither does Prausnitz. Claim 6 depends from claim 1.

As discussed above, Park does disclose each and every limitation of claim 11. Neither does Prausnitz. Claim 14 depends from claim 11

Regarding claim 23, Park does not teach or suggest hardening of the moldable materials by soft lithography as specified in amended claim 23. Neither does Smith. Claims 24-25 depend from claim 23.

Therefore, Applicants respectfully request withdrawal of this ground for rejection.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to allow this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

The Commissioner is hereby authorized to charge any underpayments or credit any over payments to Deposit Account No. 18-0580, referencing Attorney Docket No. 2335-0108.10 for any payment in connection with this communication, including any fees for extension of time, which may be required. However, an issue fee may not be charged to this account. The Examiner is invited to call the undersigned if such action might expedite the prosecution of this application.

Respectfully submitted,

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